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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,134	03/16/2004	Ruey J. Yu	BMR-010	9237
70813	7590	09/21/2007		
GOODWIN PROCTER LLP 901 NEW YORK AVENUE, N.W. WASHINGTON, DC 20001			EXAMINER HUGHES, ALICIA R	
			ART UNIT 1614	PAPER NUMBER
			NOTIFICATION DATE 09/21/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	Application No. 10/801,134	Applicant(s) YU, RUEY, ET AL	
	Examiner Alicia R. Hughes	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 4-12 and 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13-19 and 30-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 1-36 are pending presently. However claims 1-3, 13-19, and 30-36 are under consideration in this Office Action.

Claim 4-12 and 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in the replies filed on.

Applicant's election with traverse of the election and restriction requirements in the replies filed on 08 January 2007 and 01 June 2007 are acknowledged. The traversal of the restriction requirement, is treated, however, without traverse, because the Applicants have failed to disclose their grounds of traversal. The traversal of the species election is on the ground(s) that the use of the species are not relevant to the claims. This is not found persuasive because if a search for one species does not necessarily yield results for the other, based on the divergence of their applicability, as in the instant case, an undue search burden exist.

In light of the foregoing, the requirement is still deemed proper and is therefore made FINAL.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

Art Unit: 1614

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 13-19 (composition claims) and 30-36 (method claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 (composition claims) and 3-25 (method claims) of U.S. Patent No. 6,524,593 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '593 patent claims a composition for topical application to treat dermatological and/or cosmetic conditions comprising a suitable pharmaceutical carrier and a therapeutically effective

Art Unit: 1614

amount of N-acetyl-arginine. The methods articulated in claims 3-25 of the '593 patent overlap in scope with the methods articulated in claims 30-36 of the instant invention. Both sets of claims utilizing the open claim language "comprising" and involve the administration of a cosmetic composition with arginine, a skin-lightening agent, retinoic acid, and hydrocortisone, for example.

Although claims 1 and 2 do not set out the additional composition ingredients articulated in the instant application, that they are contemplated is without question given the open language, "comprising," utilized in the claim language, bringing the instant invention within the purview of the '593 patent. The aforementioned thought process is motivated by the fact that at the time the instant invention was contemplated, it was common practice in the art to administer cosmetic compositions that included arginine with a skin-lightening agent, retinoic acid, and hydrocortisone, for example. See U.S. Patent Pregrant Publication No. 2004/0116356 [hereinafter referred to as "Malik"], (Page 21, Claims 10, 11, and 13; Page 10, Paragraph 141; Page 11, Paragraph 153; Page 13, Paragraphs 184, 185, 188 and 191). In view of the foregoing, the present application is obviously a non-patentably distinct variation of the '593 patent.

Claims 1-3 and 13-19 (composition claims) and 30-36 (method claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 31-36 (composition claims) and 47-55 (method claims) of U.S. Patent Application No. 10/792,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because, for example, the '273 Application claims a method of treating a cosmetic condition by topically applying a therapeutically effective amount of composition in the form of a gel, cream, liquid, etc that comprises an alkaline pharmaceutical and an acid that

Art Unit: 1614

essentially produces the properties present in the combination of ingredients disclosed in the instant invention. As noted prior, the open language, "comprising" invites consideration of other compounds, bringing the present invention within its purview. The same applies to the remaining co-pending applications cited herein.

The composition of the '273 application contemplates ingredients present in the instant invention, such as retinoic acid, skin lightening agents, and hydrocortisone. Although claim 1 does not set out the additional composition ingredients articulated in the instant application with specificity, that they are contemplated is without question given the open language, "comprising," utilized in the claim language, bringing the instant invention within the purview of the '273 Application. The aforementioned thought process is motivated by the fact that at the time the instant invention was contemplated, it was common practice in the art to administer cosmetic compositions that included arginine with a skin-lightening agent, retinoic acid, and hydrocortisone, for example. *See* Malik, Page 21, Claims 10, 11, and 13; Page 10, Paragraph 141; Page 11, Paragraph 153; Page 13, Paragraphs 184, 185, 188 and 191. In view of the foregoing, the present application is obviously a non-patentably distinct variation of the '273 Application.

This is a provisional rejection, because the claims have not, in fact, been patented.

In looking in continuity data, it is noted that applicant has numerous issued patents and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, issued patents with the same or similar subject matter include but are not limited to 6,335,023; 6,524,593; 6,767,924; and 6,808,716. Pending

Art Unit: 1614

patent applications with the same or similar subject matter include, but are not limited to 09/513,225; 11/844,865; 09/566,374; 09/729,981; 10/626,158; 11/050,434; 11/228,230; 11/375570; 11/590,897; 11/590,898; 11/621,287; and 11/844,882.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of 35 U.S.C. 102(e) which forms the basis for all obviousness rejections set forth in this Office Action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 13-19, and 30-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Malik. as evidenced by Chen, Xin, et al., "Crystal Structure of Apo-cellular Retinoic Acid-binding Protein Type II (R111M) Suggests a Mechanism of Ligand Entry," *Jounral of Molecular Biology*, Vol. 278, pages 641-653 (1998).

Malik discloses compositions and methods that use compounds that can stimulate proliferation of fibroblasts or keratinocytes and/or stimulate the production of collagen by fibroblasts in order to treat gum and skin-related conditions (Abstract). More specifically, Malik discloses a composition and the administration thereof that can comprise hydroxy acid compound with retinoic acid (Page 21, Claims 10, 11, and 13 and Page 10, Paragraph 141), an anti-oxidant/radical scavenger, such as arginine (Page 21, Claims 10 and 11 and Page 11, Paragraph 153), a skin lightening agent (Page 21, Claims 10 and 11 and Page 13, Paragraphs 184

Art Unit: 1614

and 185), and an anti-microbial or antifungal compound, such as hydrocortisone (Page 13, Paragraphs 188 and 191) to treat skin conditions (See generally Page 2, Paragraph 20).

The composition and method of treatment in Malik discloses the active ingredients in a dermatologically acceptable carrier (Page 24, Claim 48). The methods contemplated in Malik envisage optimization of pH for the composition's application to fall into the range most suitable for the composition's use (Please see Page 9, paragraphs 125 and 126, noting the contemplation of pH adjusters), bringing it within the purview of the range limitations contemplated in claims 31 and 32 of the instant invention. The invention contemplates a composition in the form of a lotion, cream, gel or ointment (Paragraph 231) that is useful in the treatment of wounds, stimulating gum tissue growth and reversing the effects of aging on the skin (Page 1, Paragraph 8), with a topical application (Page 16, Paragraph 225). That a molecular complex is formed between the retinoic acid and arginine is inherent in the formation of the complex. *See, e.g.,* Chen, et al., *e.g.*, page 647, Col. 1, paragraphs 3 and 4.

The composition contemplated in Malik defines an effective amount of hydroxy acid as having a concentration of about 0.001 micromolar to about 10 millimolar (Page 21, Claim 8 and Claim 9) and the same as comprising from about 0.1% to about 10% of arginine (Page 11, Paragraphs 152 and 153), about 0.1% to about 10% weight of the composition a skin lightening agent (Page 13, Paragraphs 184, 185, and 189), about 0.001% to about 10% hydrocortisone (Page 13, paragraphs 189 and 191), bringing the contemplated invention, most notably claims 13, 16, and 17, within the purview of the prior art.

For the reasons set forth herein, the present invention is clearly anticipated by Malik.



Art Unit: 1614

### Conclusion

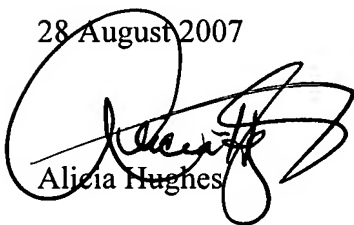
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

28 August 2007

  
Alicia Hughes

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER